Gregory D. Miller
Gene Y. Kang
RIVKIN RADLER LLP
25 Main Street, Suite 501
Court Plaza North
Hackensack, New Jersey 07601
Telephone: 201-297-2460
Facsimile: 201-489-0495

Stephen P. Benson (to be admitted *pro hac vice*)
Kimberly A. Beis (to be admitted *pro hac vice*)
FREEBORN & PETERS LLP
311 South Wacker Drive, Suite 3000
Chicago, Illinois 60606
Telephone: 312-360-6000
Facsimile: 312-360-6520

Attorneys for Plaintiffs
Sun Pharmaceutical Industries Ltd. and
Sun Pharmaceutical Industries, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SUN PHARMACEUTICAL INDUSTRIES LTD., and SUN PHARMACEUTICAL INDUSTRIES, INC., Plaintiffs, v. NOVARTIS PHARMACEUTICALS CORP., ALCON PHARMACEUTICALS LTD. and NOVARTIS AG, Defendants.	Civil Action No. _____

SUN PHARMACEUTICAL INDUSTRIES LTD. AND SUN PHARMACEUTICAL INDUSTRIES, INC.'S COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiffs Sun Pharmaceutical Industries Ltd. ("SPIL") and Sun Pharmaceutical Industries, Inc. ("SPII") (collectively, "Sun"), by and through their counsel, respectfully

submit this Complaint for Declaratory Judgment against Defendants Novartis Pharmaceutical Corp. ("Novartis"), Novartis AG, ("Novartis AG") and Alcon Pharmaceuticals Ltd. ("Alcon") (collectively, "Defendants"). In support thereof, Sun alleges as follows:

NATURE OF THE ACTION

1. This action is based on the patent laws of the United States, Title 35 of the United States Code and the Declaratory Judgment Act, 28 U.S.C. §§2201 and 2202 and seeks declaratory judgment Sun's proposed products in Abbreviated New Drug Application ("ANDA") No. 210470 do not and will not infringe any valid and enforceable claim of U.S. Patent Nos. 9,402,805 ("the '805 patent"), 9,345,714 ("the '714 patent"), 9,149,486 ("the '486 patent"), and 8,846,650 (the '650 patent") and the claims of the '805 patent are invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to, 35 U.S.C. §§ 102, 103 and/or 112, and/or based on other judicially created bases for invalidation.

THE PARTIES

2. Plaintiff SPIL is a corporation organized and existing under the laws of India, with its principal place of business in Mumbai, India.

3. Plaintiff SPII is a corporation organized and existing under the laws of the State of Michigan, United States, with its principal place of business in the Princeton, New Jersey. SPII is a wholly owned subsidiary of SPIL.

4. On information and belief, Novartis AG is a corporation organized and existing under the laws of Switzerland, having an office and place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland.

5. On information and belief, Defendant Alcon is a corporation organized and existing under the laws of Switzerland, having a principal place of business at Rue Louis d'Affry 6, 1701 Fribourg, Switzerland. On information and belief, Alcon is a wholly owned subsidiary of

Novartis AG.

6. On information and belief, Defendant Novartis Pharmaceuticals Corp. is a corporation organized and existing under the laws of the State of Delaware, having principal place of business at 59 Route 10, East Hanover, New Jersey 07936. On information and belief, Novartis Pharmaceuticals Corp. is also a wholly owned subsidiary of Novartis AG.

7. Novartis is the holder of NDA 021537 and Defendants sell Ciprodex® Sterile Otic Suspension ("Ciprodex") in this judicial district and throughout the United States.

JURISDICTION AND VENUE

8. This is a civil action regarding allegations of patent infringement arising under the patent laws of the United States, Title 35 of the United States Code, in which Sun also seeks declaratory relief under the Declaratory Judgment Act. Thus, the Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338, 2201 and 2202.

9. An actual controversy exists for declaratory judgment between Sun and Defendants by virtue of Defendants' listing of the '805, '714, '486 and '650 patents in the Orange Book for Ciprodex, Sun's filing of ANDA No. 210470 (the "Sun ANDA") with FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j) for a generic version of otic suspension formulated with dexamethasone and ciprofloxacin bioequivalent to Defendants' drug Ciprodex.

10. Sun contends it has a right to engage in making, using, offering to sell, and selling its products described in the Sun ANDA without license from Defendants.

11. This Court has personal jurisdiction over Defendants because Defendants conduct substantial business in, and have regular and systematic contact with, the state of New Jersey, including this District.

12. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because Defendants

are subject to personal jurisdiction in this District.

REGULATORY BACKGROUND

13. In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act, commonly referred to as the Hatch-Waxman Act. *See* 21 U.S.C. § 355 and 35 U.S.C. §§ 156 and 271(e). The Hatch-Waxman Act was intended to encourage generic-drug competition while leaving intact incentives for research and development of new drugs by "branded" drug companies. *See* H.R. Rep No. 98-857, pt. 1 at 14-15 (1984). The Hatch-Waxman Act was designed to stem the rising cost of prescription drugs by bringing less expensive generic drugs to market faster.

14. Pursuant to the Hatch-Waxman Act, a brand-name drug sponsor seeking FDA approval of a new drug must submit a New Drug Application ("NDA"). *See* 21 U.S.C. § 355. The NDA must include specific data concerning the safety and effectiveness of the drug, as well as identification of every patent that claims the "drug or method of using the drug."

15. The Hatch-Waxman Act simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need to file a lengthy and costly NDA in order to obtain FDA approval to sell a generic equivalent of a marketed drug. Instead, FDA provides an expedited review process by which generic manufacturers may file an Abbreviated New Drug Application ("ANDA").

16. The ANDA relies on the scientific findings of safety and effectiveness included by the brand-name drug manufacturer in the original NDA. The ANDA filer must demonstrate to FDA the proposed generic product is bioequivalent to the reference listed drug ("RLD").

17. When FDA approves a brand-name manufacturer's NDA, FDA publishes in the "Orange Book" any patents the brand-name manufacturer alleges can be reasonably asserted against a generic equivalent. 21 U.S.C. § 355(j)(7)(A)(iii). The listing of patents in the Orange

Book by FDA is a ministerial act. FDA does not check the facts supplied to it by the brand-name manufacturer.

18. After NDA approval by FDA, the NDA holder may list additional new patents in the Orange Book as being related to the drug the subject of the NDA. The brand manufacturer must certify the new patents claim either the approved drug or approved methods of the using the drug.

19. To obtain FDA approval of an ANDA (and thus the right to sell a generic version of a branded drug without receiving a license from the NDA holder), the ANDA must contain one of four certifications for each patent listed in the Orange Book for the RLD: (i) there are no patents listed in the Orange Book; (ii) any listed patent has expired; (iii) the patent will have expired before the generic manufacture is seeking to market its generic product; or (iv) the patent is invalid, unenforceable or will not be infringed by the manufacture, use or sale of the generic drug for which the ANDA is submitted. 21 U.S.C. § 355(j)(2)(A)(vii)(I-IV). The last of these is commonly referred to as a paragraph IV certification. If, however, the RLD claims a method of use for which the ANDA applicant does not seek approval, the ANDA must contain a statement that the method of use patent does not claim such a use. 21 U.S.C. § 355(j)(2)(A)(viii).

20. An ANDA applicant who files a paragraph IV certification must notify both the patent holder and NDA holder of its paragraph IV certification. *See* 21 U.S.C. § 355(J)(2)(B)(i).

21. An ANDA applicant may bring a declaratory judgment action for invalidity and/or non-infringement of an Orange Book-listed patent if the NDA holder does not sue the ANDA holder within 45 days of receiving notice of the ANDA holder's paragraph IV certification. 21 U.S.C. § 355(J)(5)(C).

SPECIFIC FACTUAL ALLEGATIONS

22. The '805 patent, entitled "Method of Treating Middle Ear Infections," was issued

on August 2, 2016. As per the face of the patent, the inventors of the subject matter claimed in the ’805 patent are G. Michael Wall and Peter J. Conroy, and Alcon is the purported assignee of record. Upon information and belief, Novartis AG is now the assignee of the ’805 patent. A true and correct copy of the ’805 patent is attached hereto as Exhibit A.

23. The ’805 patent purports to claim aqueous suspension formulations containing dexamethasone and ciprofloxacin for the treatment of middle ear infections.

24. The ’714 patent, entitled “Method of Treating Middle Ear Infections” was issued on May 24, 2016. As per the face of the patent, the inventors of the subject matter are G. Michael Wall and Peter J. Conroy, and Alcon is the purported assignee of record. Upon information and belief, Novartis AG is now the assignee of the ’714 patent. A true and correct copy of the ’714 patent is attached here to as Exhibit B.

25. The ’714 patent purports to claim a method of treating middle ear infections in a human patients diagnosed with otitis media and an open tympanic membrane.

26. The ’486 patent, entitled “Method of Treating Middle Ear Infections” was issued on October 6, 2015. As per the face of the patent, the inventors of the subject matter are G. Michael Wall and Peter J. Conroy, and Alcon is the purported assignee of record. Upon information and belief, Novartis AG is now the assignee of the ’486 patent. A true and correct copy of the ’486 patent is attached hereto as Exhibit C.

27. The ’486 patent purports to claim a method of treating patients with a middle ear infection in patients diagnosed with otitis media and an open tympanic membrane.

28. The ’650 patent, entitled “Method of Treating Middle Ear Infections” was issued on September 30, 2014. As per the face of the patent, the inventors of the subject matter are G. Michael Wall and Peter J. Conroy, and Alcon is the purported assignee of record. Upon

information and belief, Novartis AG is now the assignee of the '650 patent. A true and correct copy of the '650 patent is attached hereto as Exhibit D.

29. The '650 patent purports to claim a method of treating patients with a middle ear infection in patients diagnosed with otitis media and an open tympanic membrane.

30. Defendants market and sell otic suspension formulated with dexamethasone and ciprofloxacin under the brand name Ciprodex.

31. Defendants submitted an NDA to FDA for Ciprodex otic suspension for the treatment of acute Otitis Media in pediatric patients and acute Otitis Externa in pediatric, adult and elderly patients.[1] On information and belief, NDA No. 21537 was approved by FDA on July 18, 2003 for Ciprodex otic suspensions in the strength of ciprofloxacin 0.3% and dexamethasone 0.1%.

32. The '805, '714, '486, and '650 patents are listed in FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the "Orange Book") as covering Ciprodex otic suspension. The Sun ANDA was filed with FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j).

33. SPII is the agent for the purposes of the Sun ANDA and submitted the Sun ANDA on SPIL's behalf with FDA seeking approval to manufacture and sell generic versions of otic suspension formulated with dexamethasone and ciprofloxacin that are bioequivalent to Defendants' drug Ciprodex.

34. Defendants caused six patents to be listed in FDA's Orange Book as covering Ciprodex otic suspension: U.S. Patent No. 6,284,804 ("the '804 patent"), U.S. Patent No. 6,359,016 ("the '016 patent"), the '650 patent, the '486 patent, the '714 patent, and the '805

[1] Novartis Pharmaceuticals Corp. is listed as the owner of Defendants' NDA.

patent. As a result, under the Hatch-Waxman Act, Sun was required to submit patent certifications to the ’804, ’016, ’650, ’486, ’714, and ’805 patents.

35. The Sun ANDA contains a paragraph III certification to the ’804 and the ’016 patents certifying Sun will wait until the August 10, 2020 expiration of the ’804 and the ’016 patents to begin marketing Sun’s proposed product.

36. The Sun ANDA contains a Paragraph IV certification that Sun’s proposed product will not infringe claims 1-12, 16, 18, and 22 of the ’805 patent and/or claims 1-12, 16, 18, and 22 of the ’805 patent are invalid or unenforceable.

37. The Sun ANDA further contains a statement pursuant to 21 U.S.C. § 355(j)(2)(A)(viii) that Sun does not seek approval for a method of use covered by claims 13, 14, 15, 17, 19, 20, and 21 of the ’805 patent.

38. The Sun ANDA contains a statement pursuant to 21 U.S.C. § 355(j)(2)(A)(viii) that the ’650, ’486, and ’714 patents do not claim a use for which Sun seeks approval.

39. Pursuant to Sun’s paragraph IV certification, Sun seeks approval to engage in the commercial manufacture, use or sale of otic suspension formulated in the strength of ciprofloxacin 0.3% and dexamethasone 0.1% prior to the expiration of the ’805 patent.

40. On June 5, 2017, Sun notified Defendants of the paragraph IV certification for claims 1-12, 16, 18, and 22 of the ’805 patent and the § 355(j)(2)(A)(viii) statement with respect to claims 13, 14, 15, 17, 19, 20, and 21 of the ’805 patent, including the preliminary legal and factual basis for its position of non-infringement and invalidity and provided an Offer of Confidential Access to the Sun ANDA (the “Notice Letter”).

41. Neither Defendant requested access to the Sun ANDA under the terms of a negotiated Offer of Confidential Access, and neither Defendant sued Sun for patent infringement

within 45 days of receiving notice of Sun's paragraph IV certification.

42. As neither Defendant filed suit against Sun for patent infringement, Sun requested a covenant not to sue relating to the '805, '650, '486 and '714 patents, which Defendants have refused to provide.

43. As Defendants have not sued Sun for patent infringement nor provided a covenant not to sue, Sun files this declaratory judgment action seeking a declaration that the '805 is invalid, unenforceable and/or that Sun ANDA products will not infringe the '805 patent in order to enable Sun to bring its products to market at the earliest possible date allowed under applicable statutory and FDA regulatory provisions.

44. Sun believes the claims of the '805 patent are not infringed, are invalid and/or are unenforceable. Absent a declaration of non-infringement, invalidity and/or unenforceability, the listing of the '805 patent in the Orange Book will effectively deny Sun an economic opportunity to enter the marketplace and leave Defendants open to suing Sun at any time before the expiration of the '805 patent on September 13, 2022. Accordingly, an actual controversy exists between Sun and Defendants as to whether the Sun ANDA infringes any valid and enforceable claim of the '805 patent.

45. Sun believes the remaining claims of the '805 patent are not infringed by the Sun ANDA or Sun ANDA product as Sun does not seek approval for a method of use covered by claims 13, 14, 15, 17, 19, 20, and 21 of the '805.

46. Sun believes the claims of the '650, '486, and '714 patents are not infringed by the Sun ANDA or Sun ANDA product as those patents do not claim a use for which Sun seeks approval.

COUNT I

(DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '805 PATENT)

47. Sun hereby incorporates by reference its allegations contained in paragraphs 1 through 46 of this Complaint as though fully set forth herein.

48. This claim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Hatch-Waxman Act, 21 U.S.C. § 355(j)(5)(C).

49. Defendants have listed the '805 patent in the Orange Book as covering their Ciprodex otic suspension formulations containing dexamethasone and ciprofloxacin.

50. Sun has filed an ANDA with a paragraph IV certification stating claims 1-12, 16, 18, and 22 of the '805 patent are not infringed by Sun and/or are invalid and unenforceable.

51. Sun has filed an ANDA with a statement pursuant to 21 U.S.C. § 355(j)(2)(A)(viii) that Sun does not seek approval for a method of use covered by claims 13, 14, 15, 17, 19, 20, and 21 of the '805 patent.

52. Sun intends to sell otic suspension formulations containing dexamethasone and ciprofloxacin, as described in the Sun ANDA, when it obtains final FDA approval.

53. There is a real, actual and continuing justiciable case and controversy between Sun and Defendants regarding the infringement of the '805 patent.

54. The '805 patent will not be infringed by the manufacture, use or sale of generic otic suspension formulations containing dexamethasone and ciprofloxacin for which Sun has submitted the Sun ANDA.

55. Accordingly, Sun seeks and is entitled to a judicial declaration that the manufacture, sale or use of Sun's Ciprofloxacin 0.3% and Dexamethasone 0.1% Otic Suspension, the subject of the Sun ANDA, will not infringe, directly or indirectly, any valid

claim of the ’805 patent.

COUNT II

(DECLARATORY JUDGMENT OF INVALIDITY OF THE ’805 PATENT)

56. Sun incorporates by reference Paragraphs 1-55 of its Complaint as if fully set forth herein.

57. There is an actual, substantial and continuing case or controversy between Sun and Defendants regarding, *inter alia*, the invalidity of the ‘805 patent.

58. For at least the reasons set forth in the Notice Letter, one or more of the claims of the ‘805 patent are invalid for failure to comply with one or more of the requirements set forth in 35 U.S.C. § 101, *et. seq.*, including, e.g., §§ 102, 103, 112, and/or other judicially created bases for invalidation.

59. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. §§2201 *et seq.*, Sun is entitled to declaratory judgment that one or more claims of the ‘805 patent are invalid.

COUNT III

(DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE ’650 PATENT)

60. Sun incorporates by reference Paragraphs 1-59 of its Complaint as if fully set forth herein.

61. This claim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and/or the Hatch-Waxman Act, 21 U.S.C. § 355(j)(5)(C).

62. Defendants have listed the ’650 patent in the Orange Book as covering their Ciprodex otic suspension formulations containing dexamethasone and ciprofloxacin.

63. Sun has filed an ANDA with a statement pursuant to 21 U.S.C. § 355(j)(2)(A)(viii) that Sun does not seek approval for a method of use covered by claims of the

’650 patent.

64. Sun intends to sell otic suspension formulations containing dexamethasone and ciprofloxacin, as described in the Sun ANDA, when it obtains final FDA approval.

65. There is a real, actual and continuing justiciable case and controversy between Sun and Defendants regarding the infringement of the ’650 patent.

66. The ’650 patent will not be infringed by the manufacture, use or sale of generic otic suspension formulations containing dexamethasone and ciprofloxacin for which Sun has submitted the Sun ANDA.

67. Accordingly, Sun seeks and is entitled to a judicial declaration that the manufacture, sale or use of Sun’s Ciprofloxacin 0.3% and Dexamethasone 0.1% Otic Suspension, the subject of the Sun ANDA, will not infringe, directly or indirectly, any valid claim of the ’650 patent.

COUNT IV

(DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE ’486 PATENT)

68. Sun incorporates by reference Paragraphs 1-67 of its Complaint as if fully set forth herein.

69. This claim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and/or the Hatch-Waxman Act, 21 U.S.C. § 355(j)(5)(C).

70. Defendants have listed the ’486 patent in the Orange Book as covering their Ciprodex otic suspension formulations containing dexamethasone and ciprofloxacin.

71. Sun has filed an ANDA with a statement pursuant to 21 U.S.C. § 355(j)(2)(A)(viii) that Sun does not seek approval for a method of use covered by claims of the ’486 patent.

72. Sun intends to sell otic suspension formulations containing dexamethasone and ciprofloxacin, as described in the Sun ANDA, when it obtains final FDA approval.

73. There is a real, actual and continuing justiciable case and controversy between Sun and Defendants regarding the infringement of the ’486 patent.

74. The ’486 patent will not be infringed by the manufacture, use or sale of generic otic suspension formulations containing dexamethasone and ciprofloxacin for which Sun has submitted the Sun ANDA.

75. Accordingly, Sun seeks and is entitled to a judicial declaration that the manufacture, sale or use of Sun’s Ciprofloxacin 0.3% and Dexamethasone 0.1% Otic Suspension, the subject of the Sun ANDA, will not infringe, directly or indirectly, any valid claim of the ’486 patent.

COUNT V

(DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE ’714 PATENT)

76. Sun hereby incorporates by reference its allegations contained in paragraphs 1 through 75 of this Complaint as though fully set forth herein.

77. This claim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and/or the Hatch-Waxman Act, 21 U.S.C. § 355(j)(5)(C).

78. Defendants have listed the ’714 patent in the Orange Book as covering their Ciprodex otic suspension formulations containing dexamethasone and ciprofloxacin.

79. Sun has filed an ANDA with a statement pursuant to 21 U.S.C. § 355(j)(2)(A)(viii) that Sun does not seek approval for a method of use covered by claims of the ’714 patent.

80. Sun intends to sell otic suspension formulations containing dexamethasone and

ciprofloxacin, as described in the Sun ANDA, when it obtains final FDA approval.

81. There is a real, actual and continuing justiciable case and controversy between Sun and Defendants regarding the infringement of the ’714 patent.

82. The ’714 patent will not be infringed by the manufacture, use or sale of generic otic suspension formulations containing dexamethasone and ciprofloxacin for which Sun has submitted the Sun ANDA.

83. Accordingly, Sun seeks and is entitled to a judicial declaration that the manufacture, sale or use of Sun’s Ciprofloxacin 0.3% and Dexamethasone 0.1% Otic Suspension, the subject of the Sun ANDA, will not infringe, directly or indirectly, any valid claim of the ’714 patent.

PRAYER FOR RELIEF

WHEREFORE, Sun prays for a judgment as follows:

A. Judgment against Defendants declaring the ’805 patent is not infringed by the filing of the Sun ANDA;

B. Declaring the manufacture, marketing, use or offer for sale, sale and/or importation of the products that are the subject of the Sun ANDA have not infringed, do not infringe and would not, if marketed, infringe or induce or contribute to the infringement of any valid claim of the ’805 patent.

C. Declaring the claims of the ’805 patent are invalid;

D. Declaring the manufacture, marketing, use or offer for sale, sale and/or importation of the products that are the subject of the Sun ANDA have not infringed, do not infringe and would not, if marketed, infringe or induce or contribute to the infringement of any valid claim of the ’650 patent.

E. Declaring the manufacture, marketing, use or offer for sale, sale and/or

importation of the products that are the subject of the Sun ANDA have not infringed, do not infringe and would not, if marketed, infringe or induce or contribute to the infringement of any valid claim of the '486 patent.

F. Declaring the manufacture, marketing, use or offer for sale, sale and/or importation of the products that are the subject of the Sun ANDA have not infringed, do not infringe and would not, if marketed, infringe or induce or contribute to the infringement of any valid claim of the '714 patent.

G. Awarding Sun its costs, expenses and reasonable attorneys' fees pursuant to 35 U.S.C. § 285; and

H. Awarding Sun such other and further relief as the Court deems just and reasonable.

Dated: December 20, 2019

Respectfully Submitted:

By: s/ *Gregory D. Miller*
Gregory D. Miller
Gene Y. Kang
RIVKIN RADLER LLP
25 Main Street, Suite 501
Court Plaza North
Hackensack, New Jersey 07601
Telephone: 201-297-2460
Facsimile: 201-489-0495

Stephen P. Benson (to be admitted *pro hac vice*)
Kimberly A. Beis (to be admitted *pro hac vice*)
FREEBORN & PETERS LLP
311 South Wacker Drive, Suite 3000
Chicago, Illinois 60606
Telephone: 312-360-6000
Facsimile: 312-360-6520

Attorneys for Plaintiffs
Sun Pharmaceutical Industries Ltd. and
Sun Pharmaceutical Industries, Inc.

CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 & 40.1

Pursuant to Local Civil Rules 11.2 and 40.1, I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding.

Dated: December 20, 2019

Respectfully Submitted:

By: s/ *Gregory D. Miller*
Gregory D. Miller
Gene Y. Kang
RIVKIN RADLER LLP
25 Main Street, Suite 501
Court Plaza North
Hackensack, New Jersey 07601
Telephone: 201-297-2460
Facsimile: 201-489-0495

Stephen P. Benson (to be admitted *pro hac vice*)
Kimberly A. Beis (to be admitted *pro hac vice*)
FREEBORN & PETERS LLP
311 South Wacker Drive, Suite 3000
Chicago, Illinois 60606
Telephone: 312-360-6000
Facsimile: 312-360-6520

Attorneys for Plaintiffs
Sun Pharmaceutical Industries Ltd. and
Sun Pharmaceutical Industries, Inc.

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that plaintiff seeks, *inter alia*, declaratory relief.

Dated: December 20, 2019

Respectfully Submitted:

By: s/ *Gregory D. Miller*
Gregory D. Miller
Gene Y. Kang
RIVKIN RADLER LLP
25 Main Street, Suite 501
Court Plaza North
Hackensack, New Jersey 07601
Telephone: 201-297-2460
Facsimile: 201-489-0495

Stephen P. Benson (to be admitted *pro hac vice*)
Kimberly A. Beis (to be admitted *pro hac vice*)
FREEBORN & PETERS LLP
311 South Wacker Drive, Suite 3000
Chicago, Illinois 60606
Telephone: 312-360-6000
Facsimile: 312-360-6520

Attorneys for Plaintiffs
Sun Pharmaceutical Industries Ltd. and
Sun Pharmaceutical Industries, Inc.